UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 17, 2010

MEMORANDUM

Subject: Efficacy Review for VANTOCIL NR 3.8, .EPA Reg. No. 1258-RGGL, DP
Barcode: D375926

From: Tajah Blackburn, Team Leader
Product Science Branch
Antimicrobials Division (7510P)

7/17/10

To: Jacqueline McFarlane/Stacey Grigsby
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Applicant: Arch Chemicals, Inc.
5660 New Northside Drive, Ste. 1100
Atlanta, GA 30328

Formulation from the Label:

Active Ingredient	**% by wt.**
Didecyl dimethyl ammonium chloride	1.28 %
Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl benzyl ammonium chloride	1.28 %
Poly (iminoimidocarbonyliminoimdocarbonyl Imininohexamethylene hydrochloride)	1.28 %
Other Ingredients:	96.16 %
Total	100.00 %

I BACKGROUND

The product, VANTOCIL® NR 3.8 (EPA File Symbol 1258-RGGL), is a new product. The applicant request to register the product as an effective sanitizing rinses on previously cleaned food contact surfaces, food processing equipment and other hard surfaces in food processing locations diaries, restaurants and bars. The label states the use of the product at 0.5 ounces (oz) per gallon of water (150 ppm active), the product was evaluated with a 30 second contact time in water up to 500ppm hardness. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

The data package contained a letter from the applicant to EPA (dated March 10, 2010), EPA Form 8570-4 Confidential Statement Formula, EPA Form No. 8570-34 – Certification with Respect to Citation of Data, EPA Form No. 8570-26 – Formulator's Exemption Statement, EPA Form 8570-35 – Data Matrix, one study (MRID No. 480303-10, two reference documents (MRID Nos. 480303-11 and 480303-12), Statements of No Data Confidentiality Claims for the study, and the proposed label.

II USE DIRECTIONS

The product is designed for use as a sanitizer on dishes, glassware and utensils (at up to 600 parts per million (ppm) active). A portable water rinse is not allowed (do not rinse) when used as a sanitizer on food contact surfaces. Also, the sanitizer product is use in public eating places, dairy processing equipment, food processing equipment, utensils (at up to 600 ppm active), bottling and beverage dispensing equipment, sanitary filling of bottles or can final rinse application, for external spraying of filling and closing machines, in beer fermentation and holding tanks, in wineries for use on holding tanks, floors and processing equipment. Other uses of this product as a sanitizer in restaurants and bars, cafeterias, institutional kitchens, fast food operation and food storage, food establishments, supermarket, convenience stores, coffee shops, donut shops, bagel stores, pizza parlors, liquor stores, hotel, motels, dormitories, institutions, schools and college, churches, classrooms, community colleges, universities, food processing plants, USDA inspected food-processing facilities, dairy farms, hog farms, equine farms, poultry and turkey farms and egg processing plants, eat/poultry processing plants, meat/poultry producing establishments, mushroom farms, rendering plants, fishery, milk, citrus, wine, fruit, vegetable table, ice cream and potato processing plants and beverage plants.; food preparation and storage areas, dishes, glassware silverware, cooking utensils, eating utensils, plastic and other nonporous cutting boards, plastic and non-porous chopping blocks, coolers, ice chests, refrigerator bins used for meat, vegetables, fruit and eggs. Tupperware, kitchen equipment such as food processors, blenders, cutlery, trash compactors and other utensils, countertops (counters) Slurpee machines, stovetops (stoves, skinks (bathroom, kitchen) tub surfaces appliances, refrigerator, ice machines on surfaces composed of glass, metal, stainless steel, glazed porcelain, glazed ceramic, sealed granite, sealed marble, plastic (such as polystyrene or polypropylene) sealed limestone, sealed slate, sealed stone, sealed terra cotta, sealed terrazzo, chrome and vinyl, enameled surfaces, painted woodwork, (finished), Formica, vinyl and plastic upholstery. Directions on the proposed label provided the following instructions for preparation and use of the product as a food contact sanitizer:

Prior to application, remove gross food particles and soil by a pre-flush or pre-scrape and when necessary a pre-soak. Then thoroughly wash or flush objects with a good detergent followed by a potable water rinse before application of the sanitizing solution. Apply a use-solution of 0.5 to

2 ounces per gallon of water to the pre-cleaned hard surface, with a cloth, mop, sponge, sprayer or by immersion, thoroughly wetting surfaces. Surfaces must remain wet for at least 30 seconds followed by adequate draining and air drying. Do not rinse.

III AGENCY STANDARDS FOR PROPOSED CLAIM

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces; Additional Bacteria)

Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60 days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x 10^6/mL for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution from the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 480303-10 "Germicidal and Detergent Sanitizing Action of Disinfectants, Test Organism: *Staphylococcus aureus* (ATCC 6538), and *Escherichia coli* (ATCC 11229) for Vantocil® NR 3.8, by Joy Salverda. Study conducted at ATS Labs. Study completion date – April 5, 2007. Project Number A04795.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli (*ATCC 11229). Three batches (Batch 1, 2, and 3) of the product DS6365 were tested in according to ATS laboratory Protocol No. AUK0102709.GDST.1 (copy provided). One of product batch tested was at least 60 days old at the time of testing. The laboratory report referenced to the Sanitizing Rinses (for previously cleaned food-contact surfaces) from DIS/TSS-4. Use solutions were prepared by adding 1.0 mL of the product and 510.0 mL of 500 ppm AOAC Synthetic hard water (titrated at 503 ppm; a 1:256 dilutions). A culture of the microorganisms was prepared by using: (1) a French square bottles containing Nutrient Agar B were incubated for 23.5 hours at 35-37°C, (2) Pre-wet sterile gauge was used to filter the suspension; and (3) a 1 x 10^{10} CFU/mL were targeted. Use solutions were not tested in the presence of organic soil load. A 99.0-mL aliquot of each use solution was transferred to a 250-300 mL Erlenmeyer flask and placed in a water bath at 25.0°C. The test substance was allowed to equilibrate for ≥20 minutes. One-mL bacterial suspension was added to each flask. One-ml aliquots of the bacterium-product mixture were transferred to 9 mL of neutralized bland exactly 30 secondly following the addition of the test organism suspension. After vortex mixing, four 1.0 mL and four 0.1 mL aliquots of the neutralized test solution were plated with approximately 15-25 mL of tryptone glucose extract agar (TGEA). All plates were incubated for 44 hours at 35-

37°C. Following incubation, subcultures plates were visually examined for growth. Counted included those numbers count, purity, sterility, viability, and neutralization confirmation.

V. RESULTS

MRID Number	Organism	Batch No.	Total No. Surviving (CFU/carrier)	Microbes Initially Present	Percent Reduction
480303-10	*Staphylococcus aureus* (ATCC 6538)	Batch 1 (≥60 days old)	$<1.00 \times 10^1$	1.24×10^8	>99.999
		Batch 2	$<1.00 \times 10^1$		>99.999
		Batch 3	$<1.00 \times 10^1$		>99.999
	Escherichia coli (ATCC 11229)	Batch 1 (≥60 days old)	$<4.00 \times 10^2$	1.7×10^8	99.999
		Batch 2	9.00×10^1		99.999
		Batch 3	2.00×10^2		99.999

CFU= Colony Forming Unit

VI. CONCLUSIONS

1. The submitted efficacy data support the use of a 1:256 use dilution prepared in 500 ppm hard water of the product, DS6365, as a sanitizing rinse against the following microorganisms on pre-cleaned, hard, non-porous, food contact surfaces for a 30-second contact time:

Staphylococcus aureus	MRID 480303-10
Escherichia coli	MRID 480303-10

Bacterial reductions of at least 99.999 percent over the parallel control were observed within 30 seconds. In studies against *Staphylococcus aureus and Escherichia coli,* at least one of the three product batches tested was at least 60 days old at the time of testing. Neutralization confirmation testing met the acceptance criterion of growth within1 $\log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were reported as pure. Sterility control did not show growth.

VII. RECOMMENDATIONS

The registrant must confirm that the tested product, DS6365, is the product Vantocil NR 3.8, the subject of the current registration.

1. The proposed label claims are unacceptable regarding the use of the product at 0.5 ounces per gallon of use solution (i.e. 150 ppm) of the product, Vantocil ® NR 3.8, as a sanitizing rinse against the following microorganisms on pre-cleaned, hard, on-porous, food contact surface in the presence of 500 ppm hard water for a 30-second contact time:

Staphylococcus aureus	MRID 480303-10
Escherichia coli	MRID 480303-10

Consistent with Agency policy, the minimum contact allowed for food contact sanitizing rinses is 1 minutes (even though data must demonstrate efficacy in 30 seconds). The proposed label must be corrected accordingly.

2. The proposed label should include a **list or table** citing the product rate of active ingredients with corresponding use solution concentration instead of the product rate range of active ingredients [see page 3].

3. On page 3 of the proposed label, change the word "motets, to the word, "motels."